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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,641	08/25/2000	Ronda M. Allen	04121.0165-00000	5632
22852	7590	12/06/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			MELLER, MICHAEL V	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,641

Applicant(s)

ALLEN ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 and 19-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,10-15,17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims 3-9, 19-26 which are drawn to an invention nonelected with traverse in Paper No. 3.

The election is still proper and remains FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 10-15, 17, 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA polymerase from *Pyrococcus furiosus*, does not reasonably provide enablement for a DNA polymerase from any and all "samples". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

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The specification as filed, is enabled for a DNA polymerase from *Pyrococcus furiosus*, but is not enabled for a DNA polymerase from any and all "samples".

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all sources to see if they contained the claimed enzyme.

Applicant has only shown in their examples one source of the claimed enzyme, namely, *Pyrococcus furiosus*. With only knowing this one source it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given one particular source from which to isolate the claimed enzyme.

Applicant argues that the specification recites that recombinantly produced archaeal polymerases that are purified by the novel methods of the invention are known but the invention only shows that this type of enzyme was successfully used in the purification system.

While applicant's arguments are noted it is not clear which archaeal bacteria produce the claimed enzyme and which do not. Further, the claims are not even limited to the genres of archaeal bacteria in the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

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subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 10-15, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Bezuglyi et al. (abstract), Bernard et al. (title, abstract) or Grandogenett et al. (see whole reference, especially figure 4) taken with Arezi et al. (see whole reference, especially paragraph 28, 34, 36), Hogrefe et al. (see whole reference, especially paragraph 9), Bult et al. (see whole reference, especially col. 25, line 40-col. 26, line 17), or Hjorleifsdottir et al. (see whole reference, especially col. 19, lines 7-37).

Bezuglyi et al., Bernard et al., or Grandogenett et al. each teach a DNA polymerase being purified using Poly U Sepharose chromatography.

They do not teach specifically to do this with an archaeal polymerase but as shown by Arezi et al., Hogrefe et al., Bult et al., or Hjorleifsdottir et al. these enzymes (archaeal polymerases) are known in the art and are known to be purified.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the archaeal polymerases and cells since such cells and enzymes are well known in the art as is evidenced by Arezi et al., Hogrefe et al., Bult et al., or Hjorleifsdottir et al. and are known to be purified using chromatography.

To purify such enzymes and cells using poly U sepharose is simply the choice of the artisan in an effort to optimize the desired results. Chromatography is a well known step of purification for many protein including enzymes. To use a well known

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chromatography system such as Poly U Sephadex to purify a DNA Polymerase is known in the art. Since such enzymes are routinely purified using Poly U Sephadex chromatography, then it had to have been prima facie obvious to use the same chromatography for the same type of enzyme the **only** difference being that the enzyme came from a different source. Thus, when one of ordinary skill in the art was going to purify the archaeal polymerase he would have used the poly u sephadex since it was routinely used to purify DNA polymerases in general. The **only** difference was that the enzyme came from a different source but the enzyme is still a DNA polymerase.

Applicant argues that different types of chromatography are used for different types of enzymes, but the art is clear that it is well known to purify polymerases using Poly U sephadex chromatography. The art is also clear that archaeal polymerases are well known and well known to be purified. Thus, it is clearly within the purview of the skilled artisan in an effort to optimize the desired results to purify the archaeal polymerases using the Poly U sephadex. Once again, the only difference between the primary references and the invention is that the enzyme source is different but it is the same enzyme, namely a DNA polymerase.

Hogrefe teaches that archaeal polymerases from *Pyrococcus furiosus* are well known and come in two types both of which are known.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-

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0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael V. Meller
Primary Examiner
Art Unit 1654

MVM